

PSJ18 WALGREENS Opp Exh 10

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Sent: 9/26/2007 6:52:32 PM
Subject: DEA/Industry Conference Report
Attachments: DEA & Industry Seminar Sept 2007.doc

All-

The attached trip report highlights some of the pertinent topics/comments discussed at a recent DEA/Industry Seminar that I attended (held 9/11 and 9/12). This seminar is offered about every two years and allows industry to see some of the challenges DEA is facing, to understand their thinking on certain issues and to hear about potential changes to the regulations. Since the speakers are primarily from the DEA HQ Office, it is also an opportunity for industry to voice our concerns.

You are being sent the report because some portion of it pertains to your area of expertise and either requires action on your part or is being sent to you for informational purposes. If action is required, it is noted. Copies of some of the presentations are available, others were not provided. If you would like more information on any particular topic, please don't hesitate to contact me.

(See attached file: DEA & Industry Seminar Sept 2007.doc)

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DEA/Industry Seminar
Houston, Texas
September 11-12, 2007
Pertinent Points

Suspicious Orders – Don't confuse suspicious order report with an excessive purchase report. They are two different things. Not just over the threshold. Know your customers and be confident before you ship that they're legitimate.....Mike Mapes, DEA

Amerisource Bergen – DEA met with Amerisource (possibly suspended their license) in regards to their Orlando, FL DC. Amerisource implemented a new program as a result. They added four new people to investigate questionable customers (actually visit them) and a pharmacist who will be able to tell the company if their customers are ordering the "right" product mix and appear legitimate. They have also provided training for customers/manufacturers at trade shows and have had K. Wright of DEA provide training as well. They advise companies to review customer orders by looking for geographical trends, product mix trends (promethazine/codeine), % of cs vs non-cs, getting pictures of customer locations (prior to accepting them as new customers), having customers complete a questionnaire about their business and keeping documentation of who internally releases the order and when. All new customer accounts must be reviewed by the Security/Regulatory Compliance head (they look for duplicate accounts at the same address/locale, product mix and google search for internet sites). They have reviewed over 1000 new customers to date and will eventually be going back and reviewing existing customers. They also maintain a "Do Not Ship List" as well as use DEA's Federal Register notices.

Discussions with HDMA have also occurred regarding suspicious orders and internet pharmacies and DEA is considering clarifying the requirement for determining if an order is suspicious.

Drug Scheduling – Hydrocodone, Carisoprodol, Sibutamine, Tramadol (Ultram), Concerta (Methylphenidate XR - now CII, looking for CIII), Lisdexamfetamine (Vyvanse), Marinol.....all are pending Department of Health and Human Services (HHS) review.

Vyvanse example – get scheduling request for new products to DEA early. Can take 4-6 months for formal rulemaking. This product was approved by FDA February 23, 2007 but couldn't be launched because the drug's schedule had not been decided. The final notice was published in the Federal Register on May 3, 2007 and became effective June 4, 2007; launch of the product was delayed for four months.

Drug Scheduling, Cont.

Hydrocodone example – over 80 companies market versions of hydrocodone, 130 million prescriptions written yearly; sheer volume makes it the most diverted product. Dr. Sannerud is in favor of moving all forms to CII; comments during the conference reinforced this – more likely to happen then in past.

Marinol example – DEA has received a number of requests for clarification on this product. To make it clear - the only product that is CIII is “synthetic, in sesame oil and in a soft gelatin capsule”. Any other version (natural, other oil, other dosage form/hard gelatin) is NOT a CIII and must be treated as a CI due to the way the law is written. They have approached HHS and requested a review of this.

Dextromethorphan and two fentanyl precursors are under review as well (NPP and ANPP) – Follow up with SLC and Customer Service on this.

Quota –

Reiterated destruction does not automatically = replacement quota.

Quota requirements now include List I chemicals pseudoephedrine, phenylpropanolamine and ephedrine. If you manufacture or import these chemicals or drug products made from these chemicals, you must be registered and you must obtain a quota/provide DEA with an Annual Assessment of Needs (procurement) – Form 250. An import requires an import quota (Form 488). **Email sites and ask about their usage for the remainder of 2007 and 2008. Customers we distribute these products too need to “self certify” with DEA and receive a number when they do this. In the future, we will need to capture that number before filling an order – follow up with Mary Woods/Diane on this.**

DEA 106 Form – Working on improvements to allow electronic submission. Clarified information on form:

- Date of theft/loss field – put date discovered
- If a form needs to be amended, write the word “Amended” across the top
- Fixes to on-line form will include more room for “Remarks” and a larger selection of products from the drop down list.
- Advise you to notify police
- Number of reports does not include the one you are filing
- Value = how much did we pay, not the sale value
- Were other pharmaceuticals/merchandise taken (refers to non-cs)
- Don’t just say “Corporate Security Notified” – what did they do?
- When signing, also print name, title and date

Single Sheet 222 Order Forms – No carbon, will need to make a copy for the supplier/DEA. Trying to do away with carbon and encourage companies to use CSOS.

Internet Pharmacies – Many have state/DEA registrations, but no inspection is occurring (conveyed to Mike Mapes need to hold state's to their inspection responsibilities, not just put the blame on distributors of these products). Drugs are not cheaper on the internet as most believe! There is a considerable profit for those involved, so they feel it is worth the risk of getting caught. DEA's new strategy has been to go after those that supply the internet pharmacies. Noted many companies received suspended/revoked registrations (their names were put up on the slide). Now expect "smurfing" to occur where the internet pharmacies will buy a smaller amount of product from multiple companies to come in under the radar.

DEA WARNING! Our next strategy involves pain management clinics – many are basically pill mills. "Take heed distributors and look at these places."

CS Seminar Speakers Recruited:

Michael Mapes (will be retired in October) – SOMs and Internet pharmacies
Philippa LeVine (wants to relocate to CA) – Methamphetamine dangers
Mike (Los Angeles DEA Office) – Dinner speaker
Orlando Balcos, Strong Environmental – cs destructions

Registration Validation now available through website (talk to Diane/Mary about the need for NTIS). Can validate by DEA number only. We must have a current DEA registration to use the system.

Drug Codes – can now be changed on-line (communicate to Lynn that we still should contact the local office and give them a heads up verbally)

Hydro Abuse/Diversion in general discussed at length by all presenters (pictures of our cargo theft suspect were shown, cargo theft was discussed w/out mentioning our name, trailer abandoned so that battery would have time to die in GPS system). FBI representative (Ryan Toole) and Fed Ex White Glove Service representative (Tammy Robertson) spoke about things to do to prevent and the services Fed Ex offers. Offer dual drivers, #s on truck roof, cameras, air cup to prevent trailer from being able to dislodge from cab, drivers don't stop within 300 miles of the shipper, will hire security professionals to follow truck, dual drivers stay within 25 feet of truck at all times, have double communication capabilities, temperature/humidity tracking, drivers have criminal background checks, security training, there are no hubs, door to door delivery. Did comment on the excellent teamwork of industry and DEA to recover our truck. FBI representative said use trucking companies with a Magtec ignition control device since they can not only track the shipment, but can shut down the truck. **Provigil a problem in Florida – tell Mary/Diane.** FBI becomes involved in cargo theft if theft is interstate and/or if the value is greater than \$100,000. American Trucking Association representative was supposed to speak (was a no show).

Tom McLaughlin, DEA HQ Security discussed the pharmacy theft program.

Follow up with Customer Service re: Watch those ordering large quantities or combinations of these products, especially in Texas – promethazine, codeine, phenergan and xanax.

Spoke with Denise Curry and Mark Caverly about our Corona facility/campus registration. Requested to meet with those involved in the turn down decision. Told Head Council is the one who weighed in with a no response; they will have him at the meeting to assist. Tracey to meet with site and gather additional info from them and from the township.

Other items – Spoke with Kathy Gallagher who indicated she would check to see if DEA could supply a destruction order for our cargo theft material. Conveyed to Denise and Mark C. the importance of clearer carrier requirements for transporting controlled substances (need to be spelled out in Fed. Reg. so that they all know they have to comply to keep the business. This will also put the carriers all on the same playing field and allow extra security to be more cost competitive.

Check to see if Anda distributes methadone and if so, provide a copy of that presentation.